

**TRANSMITTAL AND NOTICE OF APPROVAL OF  
STATE PLAN MATERIAL****FOR: HEALTH CARE FINANCING ADMINISTRATION**

1. TRANSMITTAL NUMBER:

0 4 — 0 0 6

2. STATE:

HAWAII

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL  
SECURITY ACT (MEDICAID)  
MEDICAL ASSISTANCE

4. PROPOSED EFFECTIVE DATE

04/01/04

TO: REGIONAL ADMINISTRATOR  
HEALTH CARE FINANCING ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

5. TYPE OF PLAN MATERIAL (Check One):

☐ NEW STATE PLAN☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate Transmittal for each amendment)

6. FEDERAL STATUTE/REGULATION CITATION:

SECTION 1927 OF THE SOCIAL SECURITY ACT

7. FEDERAL BUDGET IMPACT:

a. FFY NONE '04 \$ (312,700)b. FFY '05 \$ (3,622,350)

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

SUPPLEMENT TO ATTACHMENT 3.1-A AND 3.1-B,  
PAGES 3.4 AND 3.59. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION  
OR ATTACHMENT (If Applicable):SUPPLEMENT TO ATTACHMENT 3.1-A AND 3.1-B,  
PAGES 3.4 AND 3.5

10. SUBJECT OF AMENDMENT:

SUPPLEMENTAL DRUG REBATE PROGRAM

11. GOVERNOR'S REVIEW (Check One):

☐ GOVERNOR'S OFFICE REPORTED NO COMMENT☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL☒ OTHER, AS SPECIFIED:

AS APPROVED BY GOVERNOR

12. SIGNATURE OF STATE AGENCY OFFICIAL:

13. TYPED NAME:

LILLIAN B. KOLLER, ESQ.

14. TITLE:

DIRECTOR

15. DATE SUBMITTED:

APR 30 2004

16. RETURN TO:

DEPARTMENT OF HUMAN SERVICES  
MED-QUEST DIVISION  
POLICY AND PROGRAM DEVELOPMENT OFFICE  
P. O. BOX 700190  
KAPOLEI, HI 96709-0190**FOR REGIONAL OFFICE USE ONLY**

17. DATE RECEIVED:

April 30, 2004

18. DATE APPROVED:

September 9, 2004

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:

April 1, 2004

21. TYPED NAME:

Linda Minamoto

20. SIGNATURE OF REGIONAL OFFICIAL:

22. TITLE Associate Regional Administrator  
Division of Medicaid & Children's Health

23. REMARKS:

Pen and Ink changes made to Item 7, pursuant to State's request via e-mail dated June 16, 2004.

**Amendment to the Supplemental Drug-Rebate Agreement  
Between  
The State of Michigan, First Health Services Corporation  
And  
[Insert Manufacturer Name]**

WHEREAS, the State of Michigan, First Health Services Corporation ("First Health"), and ("Manufacturer") have entered into a Supplemental Drug-Rebate Agreement Contract # [Insert Contract Number] (the "Agreement"), effective as of [insert date]; and

WHEREAS, the States of Vermont, Nevada, Alaska, and New Hampshire have become parties to the **Michigan Multi-State Pooling Supplemental Rebate Agreement** by executing the Addendum provided for in Section 9.9 of the Agreement; and

WHEREAS, the states of Hawaii and Tennessee have evidenced an intent to become parties to the Agreement; and

WHEREAS, the Centers for Medicare and Medicaid Services ("CMS") is now requiring certain changes to the Agreement before it will authorize them; and

WHEREAS, additional states have indicated their willingness to become Participating States, as defined in Section 3.14 of the Agreement, and thereby participate in the State Supplemental Rebates (as defined in Section 3.19 of the Agreement) available under the Agreement.

NOW, THEREFORE, IN CONSIDERATION OF THE MUTUAL COVENANTS, PROMISES, AND CONDITIONS CONTAINED HEREIN, THE PARTIES AGREE TO THE FOLLOWING AMENDMENTS TO THE AGREEMENT.

1. Section 1.1: The states of Vermont, Nevada, Alaska, and New Hampshire are added on the second line and "State" is changed to "States."
2. Any and all references to "U.S. Territories" is stricken from the entire Agreement.
3. Section 2.1: On line 3 "State" is changed to "States" and the clauses beginning immediately thereafter with "and/or" are deleted down to "Participating States" on line 8. On the third line, the words "CMS approved state-funded programs" are replaced with "non-Medicaid programs approved by CMS in the Medicaid state plan(s)".
4. Section 3.3: Is deleted in its entirety and "'Client State(s)'" is stricken from the entire agreement.
5. Section 3.11: "State" within the parentheses on line one is made "States." In line three, "HHS approved state-funded programs" is deleted and replaced with "non-Medicaid programs approved by CMS in the Medicaid state plan(s)".
6. Section 3.12: This section is deleted in its entirety. "First Health Client's States" and "FH Client's States" are stricken from this Agreement.
7. Section 3.14: This section is modified to read as follows:

“‘Participating State(s)’ means the (i) States as named in Section 1.1 hereof, and (ii) other states that, subsequent to the execution of this Agreement by the States, elect to participate under this Agreement and have all necessary authorizations and approvals from CMS to do so. Unless otherwise approved by CMS on a state-by-state basis, Participating States shall be limited to ones that have a CMS approved contract under which First Health has been engaged to provide PBA Services to that state. For each new Participating State, a unilateral amendment (“New Participating State Amendment”) to this Agreement shall be executed by the new Participating State and First Health and sent to the Manufacturer prior to the Participation Commencement Date. Each Participating State, including the new Participating State, must submit a state plan amendment adding the new Participating State to the Agreement to CMS for approval. A copy of the form Amendment is attached hereto as Exhibit A.”

8. Section 3.16: This section is modified to read as follows:

“‘Participation Commencement Date’ means the latter of the date (i) a Manufacturer’s Supplemental Covered Product is effectively placed in a Participating States Preferred Drug List Program by distribution of it (via website or otherwise) to providers and prescribers, or (ii) the New Participating State Amendment is received by the Manufacturer from a new Participating State. It is the date when the Participating States entitlement to a rebate from the Manufacturer begins to accrue.”

9. Section 3.20: On the second line: the phrase “state funded, HHS approved programs” is deleted and replaced with “non-Medicaid programs approved by CMS in the state plan(s) as provided in Section 2.1 hereof”.

10. Section 5.1: The last sentence of this section is modified to read:

“Each Participating State will notify Manufacturer and First Health, within ten (10) business days of adoption and publication of a new or revised Preferred Drug List, when Manufacturer’s Supplemental Covered Product is added to the Participating State’s Preferred Drug List by providing Manufacturer and First Health a copy of the Preferred Drug List in accordance with the notice provisions of Section 9.2 hereof.”

11. Section 8.3 is modified by deleting items (ii) and (iii) so that it now reads as follows:

“Termination by a FH Client of its PBA Services Agreement with First Health shall, as of the same termination effective date, terminate this Agreement as to that Participating State.”

12. Section 9.2: This section is modified by adding the notice addresses for Nevada, Vermont, New Hampshire, and Alaska, which are as follows:

Director of Pharmacy  
Office of Vermont Health Access  
103 South Main Street  
Waterbury, VT 05671-1201

Division of Health Care Financing and Policy  
Nevada Department of Human Resources  
Mark Willden, Director  
1100 East Williams Street  
Carson City, Nevada 89701

State of New Hampshire Department of Health and Human Services  
Commissioner John Stephen  
129 Pleasant Street  
Concord, NH 03301

Dwayne Peeples  
Director of Health Care Services  
State of Alaska Health & Social Services Department  
Health Care Services Division  
4501 Business Park Boulevard, Ste. 24  
Anchorage, AK 99503

13. Section 9.9: This section is modified to read as follows:

“This Agreement will not be altered except by (i) an amendment in writing signed by all the parties, other than (ii) in the case of the addition of a new Participating State(s), by its execution of the New Participating State Amendment, both (i) and (ii) of which shall require the approval of CMS. It is acknowledged that the intent of the previous sentence is that the addition of a new Participating State(s) by amendment shall only require the consent of First Health and the approval of CMS, not Manufacturer. Manufacturer agrees that any Participating State may be added to this Agreement by amendment and that said Participating State’s covered Medicaid (and other non-Medicaid programs approved by CMS in the Medicaid state plan(s)) lives shall apply to the provisions of Schedules 2 and 3 and will affect the rebates to all Participating States in accordance with Schedules 2 and 3. The New Participating State Amendment shall be executed by First Health and the new Participating State with a copy provided to Manufacturer for its records. Other than as stated herein, no individual is authorized to alter or vary the terms or make any representation or inducement relative to it, unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Participating State(s), First Health, and the Manufacturer.”

14. Section 9.11: In the second line, replace “other state funded” with “non-Medicaid programs approved by CMS in the Medicaid state plan(s)”.
15. Except as expressly amended herein, all other terms, conditions and provisions of the Agreement shall remain in full force and effect and the parties hereto hereby ratify and confirm the same as of the date hereof. To the extent that any provisions of this Amendment conflict with the provisions of the Agreement, the provisions of Amendment shall control.

As evidence of their agreement to the foregoing terms and conditions, the parties have signed below.

MANUFACTURER

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

Date: \_\_\_\_\_

FIRST HEALTH SERVICES CORPORATION

By: \_\_\_\_\_  
Name: Teresa R. DiMarco  
Title: President

Date: \_\_\_\_\_

STATE OF MICHIGAN, DEPARTMENT OF COMMUNITY HEALTH

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

Date: \_\_\_\_\_

STATE OF VERMONT, DEPT. OF PREVENTION, ASSISTANCE, TRANSITION AND  
ACCESS

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

Date: \_\_\_\_\_

STATE OF NEVADA, DEPARTMENT OF HEALTH CARE FINANCING AND POLICY

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

Date: \_\_\_\_\_

STATE OF ALASKA, DIVISION OF HEALTH CARE SERVICES

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

Date: \_\_\_\_\_

STATE OF NEW HAMPSHIRE DEPARTMENT OF HEALTH & HUMAN SERVICES

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

Date: \_\_\_\_\_

## **EXHIBIT A**

**New Participating State Amendment to Supplemental  
Drug-Rebate Agreement Between  
The States of Michigan, Vermont, New Hampshire, Alaska and Nevada;  
First Health Services Corporation  
And  
(Manufacturer Name ("Manufacturer"))**

WHEREAS, the State of Michigan, First Health Services Corporation ("First Health"), and Manufacturer have entered into a Supplemental Drug-Rebate Agreement (the "Agreement"), effective as of April 1, 2004; and

WHEREAS, the participating States as named in Section 8 below have become parties to the Agreement as Participating States by previous amendment or addenda; and

WHEREAS, additional states have indicated their willingness to become a new Participating State, as defined in Section 3.14 of the Agreement, and thereby participate in the State Supplemental Rebates (as defined in Section 3.19 of the Agreement) available under the Agreement.

Now, therefore, in consideration of the mutual covenants, promises, and conditions contained herein and in the Agreement, the parties agree as follows:

1. The State of Hawaii is hereby added as a party to the Agreement as a new Participating State, as defined in Section 3.14 of the Agreement.
2. This Amendment shall become effective upon the date determined in accordance with Section 3.16 of the Agreement; provided that this Amendment shall not become effective until the effective date of the state plan amendment submitted to CMS on May 24, 2004.
3. An executed copy of this Amendment shall be sent via certified mail, return receipt requested to Manufacturer's address of record as set forth in the Agreement within five (5) business days of its execution by the parties. Any notice to Participating State shall be sent to the names and address in section 9 of this Exhibit:
4. This Addendum adds a new Participating State to the Agreement and does not otherwise change or alter the Agreement. The new Participating State(s) understand(s) and agrees to be bound by the terms of the Agreement.

## EXHIBIT A

5. The undersigned State acknowledges that manufacturer rebate pricing information is confidential information under applicable Federal law and shall be exempt from public disclosure pursuant to State Code Section 92F, HRS (Uniform Information Practices Act).
6. The undersigned State represents that it has not requested authorization from CMS to include any state pharmaceutical assistance program within the rebate provisions of the Agreement. The above representation shall not prohibit the undersigned State from requesting CMS authorization to include (other) pharmaceutical assistance programs within the Agreement at a later date. Upon receipt of CMS authorization, State shall give written notice to Manufacturer of the date Manufacturer's Supplemental Covered Product is effectively placed on the preferred drug list of the undersigned State's non-Medicaid programs approved by CMS in the Medicaid state plan(s) by completing the attached Exhibit A1.
7. The approximate enrollment in the undersigned State's Medicaid program at the time of execution of this Amendment is 147,000.
8. As of the effective date of this Amendment, the following are all of the Participating States under the Agreement:

<u>Michigan</u>	<u>Alaska</u>
<u>Vermont</u>	<u>Nevada</u>
<u>New Hampshire</u>	<u>Hawaii</u>

9. The contact information for each of the Participating States listed above in section 8 and new states shall be as follows:

<b>State of Michigan</b>	Department of Community Health Medical Services Administration Attn: Dave McLaury 400 S. Pine Street Lansing, MI 48933
<b>State of Vermont</b>	Director of Pharmacy Office of Vermont Health Access 103 South Main Street Waterbury, VT 05671-1201
<b>State of Nevada</b>	Division of Health Care Financing and Policy Nevada Department of Human Resources Mark Willden, Director 1100 East Williams Street Carson City, Nevada 89701

## EXHIBIT A

**State of New  
Hampshire**

State of New Hampshire Department of Health  
and Human Services  
Commissioner John Stephen  
129 Pleasant Street  
Concord, NH 03301

**State of Alaska**

Dwayne Peebles  
Director of Health Care Services  
State of Alaska Health & Social Services Department  
Health Care Services Division  
4501 Business Park Boulevard, Ste. 24  
Anchorage, AK 99503

**State of Hawaii**

Lillian B. Koller, ESQ.,  
Director  
Department of Human Services  
P. O. Box 339  
Honolulu, HI 96809

STATE OF HAWAII,  
DEPARTMENT OF HUMAN SERVICES

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

FIRST HEALTH SERVICES CORP

By: \_\_\_\_\_

Name \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_



advisory committee to be comprised of medical and pharmaceutical professionals regarding the pharmaceutical drugs that may be placed on a Preferred Drug List.

The State will appoint a Pharmacy and Therapeutics (P&T) Committee consisting of physicians and pharmacists or utilize the Drug Utilization Review (DUR) board in accordance with federal law.

(4) Supplemental Drug Rebate Programs:

The State is in compliance with section 1927 of the Social Security Act. The State has the following policies for the Supplemental Rebate Program for the Medicaid population:

- CMS has authorized the state of Hawaii to enter into the Michigan multi-state pooling agreement. The Amendment to Supplemental Drug Rebate Agreement was submitted to CMS on May 24, 2004 and has been authorized by CMS.
- CMS has authorized Hawaii's collection of supplemental rebates through the MMSPA.
- The prior authorization process complies with the requirements of Section 1927 of the Social Security Act and provides for a turn-around response by either telephone or other telecommunications device within 24 hours of receipt of a prior authorization request. In emergency situations, providers may dispense a 72-hour supply of medication (except for those drugs that are excluded or restricted from coverage).
- Supplemental rebates received by the State in excess of those required under the National Drug Rebate Program will be shared with the Federal government on the same percentage basis as applied under the National Drug Rebate Agreement.

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TN No. 04-006

Supersedes

TN No. 04-003

Approval Date: SEP - 9 2004 Effective Date: 04/01/04

- All drugs covered by the National Drug Rebate Agreements remain available to Medicaid beneficiaries, although some may require prior authorization.
  - All drugs covered by the program, irrespective of a supplemental rebate agreement, will comply with the provisions of the national drug rebate agreement.
  - Any contracts not authorized by CMS will be submitted for CMS approval in the future.
  - The unit rebate amount is confidential and will not be disclosed except in accordance with §1927 (b)(3)(D) of the Act.
- (5) The maximum quantity of any medication to be paid equals the larger of a one month supply or one hundred units. The State may implement stricter quantity restrictions to help ensure proper utilization and reduce billing errors.
- (6) In compliance with Section 1927(b)(2) of the Social Security Act, the fiscal agent is engaged to report to each manufacturer not later than sixty days after the end of each calendar quarter and in a form consistent with a standard reporting format established by the Secretary, information on the total number of dosage units of each covered outpatient drug dispensed under the plan during the quarter and shall promptly transmit a copy of such report to the Secretary as instructed by CMS.
- 12b. Partial dentures limited to fill the space due to the loss of one or more anterior teeth and to fill the space due to the loss of two or more posterior teeth exclusive of third molars. Temporary dentures allowed only when teeth have been extracted recently with prior authorization and subject to maximums or prosthetics.
- Only one prosthetic appliances in any five year period is allowed for a maximum of one for each type, partial and full dentures, per arch per recipient; lifetime. This is allowed when present or previous dentures cannot be repaired or adjusted.
- 12c. Prosthetic devices require prior authorization when the cost of purchase, repair or manufacture exceeds \$50.00.

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TN No. 04-006

Supersedes

TN No. 03-004Approval Date: SEP - 9 2004 Effective Date: 04/01/04